UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF ALABAMA
NORTHERN DIVISION

SANDREA SMITH,	)	
	)	
PLAINTIFF,	)	Civil Action No. _____
	)	
V.	)	**JURY DEMAND**
	)	
ANGIODYNAMICS, INC. and NAVILYST MEDICAL, INC.,	)	
	)	
DEFENDANTS.	)	

COMPLAINT

COMES NOW the Plaintiff, Sandrea Smith, (hereinafter "Plaintiff"), by and through her undersigned counsel, and brings this Complaint against AngioDynamics, Inc., and Navilyst Medical, Inc., (collectively, the "Defendants"), and alleges as follows:

INTRODUCTION

1. This is an action for damages arising out of failures relating to Defendants' design, development, testing, assembling, manufacturing, packaging, promoting, marketing, distribution, supplying, and/or selling the defective implantable vascular access device sold under the trade name of Smart Port (hereinafter "Smart Port" or "Defective Device").

2. Plaintiff Sandrea Smith was implanted with one of Defendants' Smart Port devices.

3. As a direct and proximate result of Defendants' conduct and Defendants' Smart Port, Plaintiff has suffered serious and substantial life-altering injuries.

PARTIES

4. Plaintiff Sandrea Smith is an adult resident and citizen of Pike County, Alabama.

5. Defendant AngioDynamics, Inc. ("AngioDynamics") is and, at all times relevant, was a Delaware corporation with its principal place of business located in Latham, New York. AngioDynamics is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its medical devices, including the Smart Port. AngioDynamics may be served through its agent Corporation Service Company, 641 South Lawrence Street, Montgomery, Alabama 36104.

6. Defendant Navilyst Medical, Inc. ("Navilyst") is and, at all times relevant, was a Delaware corporation with its principal place of business located in Marlborough, Massachusetts. Navilyst conducts business throughout the United States, including the State of Alabama, and is a wholly owned subsidiary of AngioDynamics. Navilyst is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its medical devices, including the Smart Port.

JURISDICTION AND VENUE

7. At all times pertinent to this Complaint, Defendants were the mere alter egos or instrumentalities of each other. There is such a unity of interest and ownership between Defendants that the separate personalities of their entities ceased to exist.

8. At all times pertinent to this Complaint, Defendants acted in all respects as agents or apparent agents of one another.

9. Defendants regularly transact business in Alabama that includes marketing and selling vascular access devices, derive substantial revenue from their business transactions in Alabama, and have purposely availed themselves of the privilege of doing business in Alabama.

10. Defendants' actions in marketing and selling their devices in Alabama should have led them to reasonably anticipate being hauled into Court in Alabama.

11. Defendants have sufficient "minimum contacts" with Alabama that subjecting them to personal jurisdiction in Alabama does not offend traditional notions of fair play and substantial justice.

12. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. §1332, because the amount in controversy exceeds $75,000.00, exclusive of interest and costs, and because Defendants are incorporated and have their principal places of business in states other than the state in which Plaintiff resides.

13. Venue is proper in this Court pursuant to 28 U.S.C. §1391 because a substantial part of the events or omissions giving rise to Plaintiff's claims occurred, in part, in this District, and because Defendants conducted regular business in this District.

PRODUCT BACKGROUND

14. Defendants received clearance via the 510(k) Premarket Notification Program from the Food and Drug Administration ("FDA") to market and sell Smart Port devices.

15. Section 510(k) of the Medical Device Amendments to the Food, Drug, and Cosmetics Act permits the marketing of medical devices if the device is substantially equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of the device.

16. Defendants' implantable port devices, including the Smart Port, were designed, patented, manufactured, labeled, marketed, sold, and distributed by the Defendants at all relevant times herein.

17. The Smart Port is one of several varieties of port/catheter systems that has been designed, manufactured, marketed, and sold by Defendants.

18. According to Defendants, the Smart Port is a totally implantable vascular access device designed to provide repeated access to the vascular system for the delivery of medication, intravenous fluids, parenteral nutrition solutions, and blood products.

19. The intended purpose of the Smart Port is to make it easier to deliver medications directly into the patient's bloodstream. The device is surgically placed completely under the skin and left implanted.

20. The Smart Port is a system consisting of two primary components: an injection port and a silicone catheter which includes additives intended to make it radiopaque.

21. The injection port has a raised center, or "septum," where the needle is inserted for delivery of the medication. The medication is carried from the port into the bloodstream through a small, flexible tube, called a catheter, that is inserted into a blood vessel.

22. According to Defendants' marketing materials, the Fluoromax™ Catheter is a high-radiopacity catheter made from 100% silicone.

23. The Fluoromax™ Catheter is comprised of a polymeric mixture of silicone and a barium sulfate radiopacity agent.

24. Barium sulfate is known to contribute to reduction of the mechanical integrity of silicone *in vivo* as the particles of barium sulfate dissociate from the surface of the catheter over time, leaving microfractures and other alterations of the polymeric structure and degrading the mechanical properties of the silicone.

25. Researchers have shown that catheter surface degradation in products featuring a radiopaque barium sulfate stripe is concentrated at the locus of the stripe.[1]

26. The mechanical integrity of a barium-sulfate-impregnated silicone is affected by the concentration of barium sulfate as well as the heterogeneity of the modified polymer.

27. Upon information and belief, Defendants' manufacturing process in designing and constructing the catheter component of the Smart Port implanted in Plaintiff involved too high a concentration of barium sulfate particles for the polymer formulation, leading to improperly high viscosity of the admixed silicone before polymerization and causing improper mixing of barium sulfate particles within the polymer matrix.

28. This defect in the manufacturing process led to a heterogeneous modified polymer which included weakened areas at the loci of higher barium sulfate concentration and led to fracture of the catheter.

29. Although the surface degradation and resultant mechanical failure can be reduced or avoided with design modifications (e.g., using a higher grade radiopacity compound and/or encapsulating the admixed polymer within an outer layer of pristine polymer), Defendants elected not to incorporate those design elements into the Smart Port.

30. At all times relevant, Defendants misrepresented the safety of the Smart Port devices, and negligently designed, manufactured, prepared, compounded, assembled, processed, labeled, marketed, distributed, and sold the Smart Port as safe and effective devices to be surgically implanted to provide repeated access to the vascular system for the delivery of medications, intravenous fluids, parenteral nutrition solutions, and blood products.

[1] *See* Hecker JF, Scandrett LA. Roughness and thrombogenicity of the outer surfaces of intravascular catheters. *J Biomed Mater Res*. 1985;19(4):381-395. doi:10.1002/jbm.820190404.

31. At all times relevant to this action, Defendants knew and had reason to know, that the Smart Port was not safe for the patients for whom they were prescribed and implanted, because once implanted the devices were prone to fracturing, migrating, perforating internal vasculature, and otherwise malfunctioning.

32. At all times relevant to this action, Defendants knew and had reason to know that patients implanted with a Smart Port had an increased risk of suffering life threatening injuries, including but not limited to: death; fracture; hemorrhage; cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart); cardiac arrhythmia and other symptoms similar to myocardial infarction; severe and persistent pain; and perforations of tissue, vessels and organs, or the need for additional surgeries or procedures to remove the defective devices.

33. Soon after the Smart Port was introduced to market, which was years before Plaintiff was implanted with her device, Defendants began receiving large numbers of adverse event reports ("AERs") from health care providers reporting that the Smart Port was fracturing post-implantation and that fractured pieces were migrating throughout the human body, including to the heart and lungs. Defendants also received large numbers of AERs reporting that the Smart Port was found to have perforated internal vasculature. These failures were often associated with reports of severe patient injuries such as:

a. Hemorrhage;

b. Fracture and migration;

c. Cardiac/pericardial tamponade;

d. Cardiac arrhythmia and other symptoms similar to myocardial infarction;

e. Severe and persistent pain;

f. Perforations of tissue, vessels and organs; and

g. Upon information and belief, even death.

34. In addition to the large number of AERs which were known to Defendants and reflected in publicly accessible databases, there are many recorded device failures and/or injuries related to the Defendants' implantable port devices which were concealed from medical professionals and patients through submission to the FDA's controversial Alternative Summary Reporting ("ASR") program.

35. The FDA halted the ASR program after its existence was exposed by a multi-part investigative piece, prompting a widespread outcry from medical professionals and patient advocacy groups.[2]

36. Prior to the discontinuation of the ASR program, Defendants reported numerous episodes of failures of their implantable port devices – including numerous episodes of catheter fracture – under the ASR exemption, thereby concealing them from physicians and patients.

37. Defendants were aware or should have been aware that the Smart Port had a substantially higher failure rate than other similar devices on the market, yet Defendants failed to warn consumers and physicians of this fact.

38. Defendants also intentionally concealed the severity of complications caused by the Smart Port and the likelihood of these events occurring.

39. Rather than alter the design of the Smart Port to make it safer or adequately warn physicians of the dangers associated with the Smart Port, Defendants continued to actively and aggressively market the Smart Port as safe, despite their knowledge of numerous reports of catheter fracture and associated injuries.

[2] Christina Jewett, *Hidden Harm: Hidden FDA Reports Detail Harm Caused by Scores of Medical Devices*, Kaiser Health News (Mar. 2019).

40. Moreover, Defendants' messaging and other communications suggested that fracture of the catheter component of the Smart Port could only occur if the physician incorrectly placed the device such that undue catheter compression or "pinch-off" was allowed to occur. In reality, Defendants knew internally these devices were fracturing and causing serious injuries due to defects in the design, manufacturing and lack of adequate warnings.

41. Defendants provided incomplete, insufficient, and misleading information to physicians in order to increase the number of physicians using Smart Port for the purpose of increasing their sales. By so doing, Defendants caused the dissemination of inadequate and misleading information to patients, including the Plaintiff.

42. The conduct of Defendants, as alleged in this Complaint, constitutes willful, wanton, gross, and outrageous corporate conduct that demonstrates a conscious disregard for the safety of Plaintiff and evidence of malice, fraud, gross negligence, and oppressiveness.

43. Defendants had actual knowledge of the dangers presented by the Smart Port, yet consciously failed to act reasonably to:

a. Adequately inform or warn Plaintiff, her prescribing physicians, or the public at large of these dangers;

b. Establish and maintain an adequate quality and post-market surveillance system; or

c. Recall the Smart Port from the market.

44. Despite knowing that the Smart Port devices were prone to fracturing and migration, Defendants failed to design and establish a safe, effective procedure for removal of the Smart Port. Therefore, in the event of a failure, injury, or complications it is difficult to safely remove Smart Port.

SPECIFIC FACTUAL ALLEGATIONS AS TO PLAINTIFF SANDREA SMITH

45. On or about April 28, 2021, Plaintiff Sandrea Smith underwent placement of Defendants' Smart Port device, UPN number H787CT75STSD0, Lot number 5596070. The device was implanted by Dr. LeRoy W. Hodges at Troy Regional Medical Center in Troy, Alabama.

46. During the surgery to implant the Smart Port, Dr. Hodges confirmed proper placement of the Smart Port with fluoroscopy. Dr. Hodges did not note any complications during placement of the Smart Port and noted that Plaintiff was taken to the recovery room in stable condition.

47. Plaintiff underwent implantation of Defendants' Smart Port device to aid in the administration of her infusion therapy for thrombotic thrombocytopenic purpura.

48. Defendants, directly or through their agents, apparent agents, servants, or employees designed, manufactured, marketed, advertised, distributed and sold the Smart Port that was implanted in Plaintiff.

49. Defendants manufactured, sold, and/or distributed the Smart Port to Plaintiff, through her physicians and medical providers.

50. On or about February 23, 2022, Plaintiff was undergoing infusion therapy at Troy Regional Medical Center when she suddenly experienced an immediate sharp pain in her chest.

51. Plaintiff underwent imaging, which demonstrated a catheter fracture. Imaging showed that the catheter component of the Smart Port had fractured and a piece (or pieces) of the catheter had become positioned in Plaintiff's heart.

52. Upon discovery of the fracture, Plaintiff was life-flighted from Troy Regional Medical Center to Baptist Medical Center South in Montgomery, Alabama where she was admitted at approximately 12:56 p.m. on February 23, 2022.

53. Plaintiff subsequently underwent two procedures to remove fragments of the fractured catheter from her heart.

54. Plaintiff was discharged from Baptist Medical Center South on February 25, 2022.

55. At all times, the Smart Port was utilized and implanted in a manner foreseeable to Defendants, as Defendants generated the instructions for use and created procedures for implanting the Smart Port.

56. The Smart Port implanted in Plaintiff was in the same or substantially similar condition as when it left the possession of Defendants and in the condition directed by and expected by Defendants.

57. Plaintiff and her physicians foreseeably used and implanted the Smart Port in accordance with Defendants' instructions and did not misuse or alter the Smart Port in an unforeseeable manner.

58. Defendants advertised, promoted, marketed, sold, and distributed the Smart Port as a safe medical device when Defendants knew or should have known the Smart Port was not safe for its intended purposes and that the devices could cause serious medical problems.

59. Defendants had sole access to material facts concerning the defective nature of the Smart Port devices and their propensity to cause serious and dangerous side effects.

60. In reliance on Defendants' representations, Plaintiff's doctor was induced to and did use the Smart Port.

61. In reliance on Defendants' representations, Plaintiff consented to undergo implantation of the Smart Port.

62. Defendants' Smart Port was marketed to the medical community and to patients as a safe, effective, reliable, medical device implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical conditions, and as safer and more effective as compared to the traditional products and procedures for treatment and other competing implantable port devices and vascular access devices.

63. Defendants have marketed and sold the Smart Port to the medical community at large and patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to, direct to consumer advertising, aggressive marketing to health care providers at medical conferences, hospitals, private offices, and/or group purchasing organizations, and include a provision of valuable consideration and benefits to the aforementioned.

64. The injuries, conditions, and complications suffered due to Defendants' Smart Port devices include, but are not limited to, hemorrhage, fracture and migration, cardiac/pericardial tamponade, cardiac arrhythmia and other symptoms similar to myocardial infarction, severe and persistent pain, perforations of tissue, vessels and organs, and, upon information and belief, even death.

65. Neither Plaintiff nor her physicians were aware, by warning or otherwise, of the defects of Defendants' Smart Port, and would not have used and/or consented to undergo implantation of the Smart Port had they been aware of the defective nature of the device.

66. At the time of her operation, Plaintiff was not informed of, and had no knowledge of the complaints, known complications, and risks associated with Smart Port, including but not

limited to its propensity to fracture or break and cause pieces of the device to migrate to other major organs such as the heart.

67. Plaintiff was never informed by Defendants of the defective and dangerous nature of Smart Port.

68. As a result of having the Smart Port implanted, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, permanent and substantial physical deformity, has undergone corrective procedures, and has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses.

COUNT I
ALABAMA EXTENDED MANUFACTURER'S LIABILITY DOCTRINE (AEMLD)
(Against Defendants AngioDynamics and Navilyst)

69. Plaintiff incorporates the preceding paragraphs as if set out fully herein.

70. At all times herein mentioned, Defendants are the researchers, designers, manufacturers, testers, advertisers, promoters, marketers, packagers, labelers, sellers and/or distributors of the Smart Port, which is defective and unreasonably dangerous.

71. The Smart Port is defective in its design or formulation in that it is not reasonably fit, suitable or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design. The Smart Port is defective in design because it lacks efficacy, has a high failure rate, poses a greater likelihood of injury, is more dangerous than other available implantable port devices and vascular access devices indicated for similar conditions and uses, and the utility of the Smart Port does not outweigh its risks.

72. The defective condition of the Smart Port rendered it unreasonably dangerous and/or not reasonably safe, and the Smart Port was in this defective condition at the time it left the hands of Defendants. The Smart Port was expected to and did reach Plaintiff and her physician

without substantial change in the condition in which it was designed, manufactured, labeled, sold, distributed, marketed, promoted, supplied, and otherwise released into the stream of commerce.

73. The Smart Port was used for its intended purposes and the device was not materially altered or modified prior to its use.

74. The Smart Port is defective in design because the process by which the catheter component is constructed causes degradation and a reduction of the mechanical integrity of the catheter.

75. The Smart Port is defective in design because the compromised mechanical integrity of the catheter component makes the device more prone to fracture, migrate, perforate internal vasculature, and otherwise malfunction requiring surgery and other procedures to remove the device at an unreasonably greater rate than other implantable port devices.

76. At or before the time the Smart Port was released on the market and/or implanted in Plaintiff, Defendants could have designed the Smart Port to make it less prone to degrade and fracture, and there was a practical, technically feasible safer alternative design that would have prevented the harm Plaintiff suffered without substantially impairing the function of the device.

77. The Smart Port is and was being used in Defendants' intended manner at the time it was surgically implanted into Plaintiff and during the time it remained in Plaintiff.

78. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use and breached this duty.

79. Defendants knew or should have known that the Smart Port would be implanted in patients and that physicians and patients were relying on them to furnish a suitable product. Further, Defendants knew or should have known that patients in whom the Smart Port would be

implanted, such as Plaintiff, could be and would be injured by the defective design and composition of the Smart Port.

80. Defendants researched, designed, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which, when used in its intended or reasonably foreseeable manner, created an unreasonable risk to the health of consumers, such as Plaintiff, and Defendants are therefore liable for the injuries sustained by Plaintiff.

81. As a direct and proximate result of the Smart Port's aforementioned defects, Plaintiff suffered serious physical and mental injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

82. Defendants directly advertised and/or marketed the Smart Port to health care professionals and consumers, including Plaintiff and Plaintiff's physicians, and therefore had a duty to warn of the risks associated with the use of the Smart Port. Defendants breached this duty.

83. At the time Defendants designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the Smart Port into the stream of commerce, the Smart Port was defective and presented a substantial danger to users of the device when put to its intended and reasonably anticipated use, namely as an implanted port/catheter system to administer the medications. Defendants failed to adequately warn of the Smart Port's known or reasonably scientifically knowable dangerous propensities and further failed to adequately provide instructions on the safe and proper use of the device.

84. Defendants knew or should have known at the time they manufactured, labeled, distributed and sold the Smart Port that was implanted into Plaintiff that the Smart Port posed a significant and higher risk than other similar devices of device failure and resulting serious injuries.

85. Defendants further knew that Smart Port devices were fracturing and migrating for reasons other than "pinch-off" caused by the physician's initial placement of the device.

86. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the Smart Port. No reasonable health care provider, including Plaintiff's, and no reasonable patient would have used the Smart Port in the manner directed, had those facts been made known to the prescribing healthcare providers or patients.

87. The Smart Port was not accompanied by proper warnings and instructions to physicians and the public regarding potential adverse side effects associated with the Smart Port and the comparative severity and duration of such adverse side effects.

88. When Plaintiff was implanted with the Smart Port, Defendants failed to provide adequate warnings, instructions, or labels regarding the severity and extent of health risks posed by the device, as discussed herein.

89. The health risks associated with the Smart Port as described herein are of such a nature that ordinary patients and consumers would not have readily recognized the potential harm.

90. The Smart Port was defective at the time of release into the stream of commerce due to inadequate warnings, labeling and/or instructions accompanying the device.

91. Defendants intentionally underreported the number and nature of adverse events associated with fracture and migration of the Smart Port to Plaintiff's health care providers, as well as the FDA.

92. Neither Plaintiff nor her health care providers knew of the substantial danger associated with the intended and foreseeable use of the Smart Port as described herein.

93. Plaintiff and her health care providers used the Smart Port in a normal, customary, intended, and foreseeable manner, namely as a surgically placed device used to make it easier to

deliver medications directly into the Plaintiff's bloodstream. Moreover, Plaintiff's health care providers did not place or maintain the device incorrectly such that it caused the device to "pinch off" or otherwise malfunction.

94. Upon information and belief, the defective and dangerous condition of the Smart Port devices, including the one implanted into Plaintiff, existed at the time they were manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold by Defendants to distributors and/or healthcare professionals or organizations. Upon information and belief, the Smart Port implanted in Plaintiff was in the same condition as when it was manufactured, inspected, marketed, labeled, promoted, distributed and sold by Defendants.

95. As a direct and proximate result of Defendants' lack of sufficient warnings and/or instructions, Plaintiff suffered serious physical and mental injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, and severally, and requests compensatory damages, together with costs and interest, and any further relief as the Court deems proper.

COUNT II
NEGLIGENCE
(Against Defendants AngioDynamics and Navilyst)

96. Plaintiff incorporates the preceding paragraphs as if set out fully herein.

97. Defendants owed Plaintiff a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, selling, and conducting post-market surveillance of the Smart Port.

98. Defendants failed to exercise due care under the circumstances and therefore breached this duty by:

a. Failing to properly and thoroughly test the Smart Port before releasing the device to market, and/or failing to implement feasible safety improvements;

b. Failing to properly and thoroughly analyze the data resulting from any pre-market testing of the Smart Port;

c. Failing to conduct sufficient post-market testing and surveillance of the Smart Port;

d. Designing, manufacturing, marketing, advertising, distributing, and selling the Smart Port to health care providers and patients/consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of the Smart Port, including but not limited to, its propensity to fracture and migrate, and without proper instructions to avoid the harm which could foreseeably occur as a result of using the device;

e. Failing to exercise due care when advertising and promoting the Smart Port; and

f. Negligently continuing to manufacture, market, advertise, and distribute the Smart Port after Defendants knew or should have known of its adverse effects.

99. In performing the foregoing acts, omissions, and misrepresentations, Defendants acted grossly negligent, fraudulently, and with malice.

100. As a direct, actual, and proximate cause of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered serious physical and mental injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, and severally, and requests compensatory damages, together with costs and interest, and any further relief as the Court deems proper.

COUNT III
BREACH OF IMPLIED WARRANTY
(Against Defendants AngioDynamics and Navilyst)

101. Plaintiff incorporates preceding paragraphs as if set out fully herein.

102. Defendants were the seller of the Smart Port and sold the Smart Port to Plaintiff and/or Plaintiff's physician to be implanted in Plaintiff.

103. Defendants impliedly warranted that the Smart Port was merchantable and fit for the ordinary purposes for which it was intended.

104. When the Smart Port was implanted in the Plaintiff, it was being used for the ordinary purposes for which it was intended.

105. Plaintiff, individually and/or by and through her physician, relied upon Defendants' implied warranties of merchantability in consenting to have the Smart Port implanted in her.

106. Privity exists between Plaintiff because Plaintiff's physicians acted as Plaintiff's purchasing agents in the subject transaction and/or because Plaintiff was a third-party beneficiary of the subject contract.

107. Defendants breached these implied warranties of merchantability because the Smart Port implanted in Plaintiff was neither merchantable nor suited for its intended uses as warranted in that the device varied from its intended specifications, which included, but were not limited to, variances in the following respects:

a. Defendants' manufacturing process in constructing the catheter of the Smart Port implanted in Plaintiff involved too high of a concentration of barium

sulfate particles for the polymer formulation, which led to improperly high viscosity of the admixed silicone before polymerization and causing improper mixing of barium sulfate particles within the polymer matrix;

b. Defendants' knew or should have known barium sulfate is known to contribute to a reduction in the mechanical integrity of the silicone in its device, the Smart Port, as the barium sulfate particles dissociate from the surface of the catheter over time; and

c. These defects led to a heterogenous modified polymer that included microfractures and weakened areas at the location of the higher barium sulfate concentration that ultimately led to fractures of the Smart Port and migration of catheter fragments.

108. Defendants' breaches of their implied warranties resulted in the implantation of unreasonably dangerous and defective Smart Port in the Plaintiff's body, placing Plaintiff's health and safety in jeopardy.

109. As a direct, actual, and proximate cause of Defendants' breaches of the aforementioned implied warranties, Plaintiff suffered serious physical and mental injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, and severally, and requests compensatory damages, together with costs and interest, and any further relief as the Court deems proper.

COUNT IV
BREACH OF EXPRESS WARRANTY
(Against Defendants AngioDynamics and Navilyst)

110. Plaintiff incorporates the preceding paragraphs as if set out fully herein.

111. Defendants, through their officers, directors, agents, representatives, written literature and packaging, and written and media advertisements, expressly warranted to Plaintiff, Plaintiff's healthcare providers and implanting physician, that the Smart Port was safe and fit for use by consumers, was of merchantable quality, did not produce dangerous side effects, and was adequately tested and fit for its intended use.

112. The Smart Port does not conform to the Defendants' express representations because it is not reasonably safe, has numerous serious side effects, and causes severe and permanent injuries.

113. At all relevant times, the Smart Port did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

114. Plaintiff, her physicians, and the medical community reasonably relied upon the Defendants' express warranties for the Smart Port.

115. At all relevant times, the Smart Port was used on Plaintiff by Plaintiff's physicians for the purpose and in the manner intended by Defendants.

116. Plaintiff and Plaintiff's physicians, by the use of reasonable care, could not have discovered the breached warranty and realized its danger.

117. As a direct, actual, and proximate cause of the breach of Defendants' express warranties, Plaintiff suffered serious physical and mental injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, and severally, and requests compensatory damages, together with costs and interest, and any further relief as the Court deems proper.

COUNT V
WANTONNESS
(Against Defendants AngioDynamics and Navilyst)

118. Plaintiff incorporates the preceding paragraphs as if set out fully herein.

119. Defendants had a duty to exercise reasonable and ordinary care in designing, researching, testing, manufacturing, marketing, supplying, promoting, distributing, approving, and selling the Smart Port.

120. Defendants failed to exercise ordinary care and acted with reckless indifference and conscious disregard in designing, researching, testing, manufacturing, marketing, supplying, promoting, distributing, approving, and selling of the Smart Port, in that Defendants knew or should have known that the devices created a high risk of unreasonable, dangerous side effects, including the propensity to fracture and migrate, thereby breaching their duty to consumers, including Plaintiff.

121. Defendants were consciously aware and recklessly indifferent to the fact that their following acts and/or omissions would likely and probably result in injury to consumers implanted with the Smart Port, including Plaintiff:

a. Negligently and/or wantonly designing the Smart Port in a manner which was dangerous to those individuals who had the device surgically implanted;

b. Designing, manufacturing, producing, creating and/or promoting the Smart Port without adequately testing it;

c. Failing to adequately and correctly warn Plaintiff and her physicians, hospitals, and/or healthcare providers of the dangers of the Smart Port;

d. Failing to recall their dangerous and defective Smart Port at the earliest date that it became known that the device was, in fact, dangerous and defective;

e. Advertising and/or marketing the use of the Smart Port despite the fact that Defendants knew or should have known of its defects;

f. Representing that the Smart Port was safe for its intended purpose when, in fact, it was unsafe;

g. Manufacturing the Smart Port in a manner which was dangerous to those individuals who had it implanted; and

h. Under-reporting, underestimating, and/or downplaying the serious danger of the Smart Port.

122. Upon information and belief, Defendants continued to market, manufacture, distribute and/or sell the Smart Port to consumers, including Plaintiff, despite the fact that Defendants knew or should have known that the Smart Port caused unreasonable, dangerous defects, including defects that led to fracturing and migrating, when there were safer alternative designs available.

123. At all material times, Defendants knew of the defective nature of the Smart Port as set forth herein, and continued to design, manufacture, market and sell it so as to maximize sales and profits at the expense of public health and safety, and as such Defendants' conduct exhibited a wanton and reckless disregard for human life.

124. Additionally, Defendants recklessly, knowingly, intentionally and fraudulently concealed and suppressed adverse information relating to the safety and performance of the Smart

Port from the medical community and the general public, including Plaintiff and Plaintiff's healthcare providers.

125. Defendants' misrepresentations were communicated to the medical community and the general public, including Plaintiff and Plaintiff's healthcare providers, who would rely on such in selecting the Smart Port.

126. Defendants conducted sales and marketing campaigns to promote the sale of the Smart Port and in doing so, misrepresented to Plaintiff and Plaintiff's physicians the health risks and consequences associated with using the Smart Port by publishing false, deceptive, misleading, and untruthful statements.

127. Plaintiff and/or Plaintiff's physicians justifiably relied to their detriment upon Defendants' misrepresentations and omissions in their marketing, advertisements, promotions and labeling concerning these products.

128. As a direct and proximate result of Defendants' conduct, Plaintiff suffered serious physical and mental injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, and severally, and requests compensatory damages, together with costs and interest, and any further relief as the Court deems proper.

PUNITIVE DAMAGES

129. Plaintiff incorporates the preceding paragraphs as if set out fully herein.

130. Plaintiff is entitled to an award of punitive and exemplary damages based upon Defendants' intentional, willful, knowing, fraudulent, malicious acts, omissions, and conduct, and their complete and total reckless disregard for the public safety and welfare.

131. Defendants intentionally and fraudulently misrepresented facts and information to both the healthcare community and the general public, including Plaintiff and her health care providers, by making intentionally false and fraudulent misrepresentations about the safety and efficacy of the Smart Port.

132. Defendants intentionally concealed the true facts and information regarding the serious risks of harm associated with the implantation of the Smart Port, and intentionally downplayed the type, nature, and extent of the adverse side effects of being implanted with the device, despite Defendants' knowledge and awareness of the serious and permanent side effects and risks associated with use of same.

133. Defendants further intentionally sought to mislead health care providers and patients, including Plaintiff and her health care providers, regarding the cause of failures of the Smart Port.

134. Defendants had knowledge of, and were in possession of evidence demonstrating that, the Smart Port caused serious physical side effects. Nonetheless, Defendants continued to market the Smart Port by providing false and misleading information with regard to the device's safety and efficacy to the regulatory agencies, the medical community, and consumers of the device.

135. Defendants failed to provide accurate information and warnings to the healthcare community that would have dissuaded physicians from surgically implanting the Smart Port and consumers from agreeing to being implanted with the Smart Port, thus depriving physicians and consumers from weighing the true risks against the benefits of prescribing and implanting the device.

136. Consequently, Defendants are liable for punitive damages in an amount to be determined by the jury.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against the Defendants jointly and severally for damages, including punitive damages if applicable, to which she is entitled by law, as well as all costs of this action, interest and attorneys' fees, to the full extent of the law, whether arising under the common law and/or statutory law, including:

a. Judgment for Plaintiff and against Defendants;

b. Damages to compensate Plaintiff for his injuries, economic losses and pain and suffering sustained as a result of the use of Defendants' subject device;

c. Pre and post judgment interest at the lawful rate;

d. Punitive damages, if applicable, on all applicable Counts as permitted by the law;

e. A trial by jury on all issues of the case;

f. An award of attorneys' fees; and

g. For any other relief as this Court may deem equitable and just, or that may be available under the law of another forum to the extent the law of another forum is applied, including but not limited to all reliefs prayed for in this Complaint and in the foregoing Prayer for Relief.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all counts and as to all issues.

Dated: February 15, 2024

Respectfully Submitted,

By: */s/ Frederick B. Darley, III*

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